UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF OHIO
WESTERN DIVISION

CHRISTIAN MARCUM,	:	Case No. 1:12-cv-834
	:	
Plaintiff,	:	Judge Timothy S. Black
	:	
vs.	:	
	:	
DEPUY ORTHOPEDICS, INC.,	:	
	:	
Defendant.	:	

ORDER GRANTING IN PART AND DENYING IN PART DEFENDANT'S MOTION TO DISMISS (Doc. 7)

This civil action is before the Court on Defendant's motion to dismiss (Docs. 7, 8) and the parties' responsive memoranda. (Docs. 12, 13). This prescription medical device case arises from a ceramic femoral head component that broke four years after Plaintiff's total hip replacement surgery. Plaintiff has asserted claims for strict liability (defective manufacturing, defective design, and nonconformance with representations), common law negligence, breach of express warranty, breach of implied warranty, and negligent misrepresentation, and Plaintiff seeks punitive damages in her prayer for relief. (Doc. 1 at ¶¶ 13-21).

I. FACTS AS ALLEGED BY THE PLAINTIFF

For purposes of this motion to dismiss, the Court must: (1) view the complaint in the light most favorable to Plaintiff; and (2) take all well-pleaded factual allegations as true. *Tackett v. M&G Polymers*, 561 F.3d 478, 488 (6th Cir. 2009).

Defendant is responsible for the design, manufacturing, marketing, distribution, and sale of the DePuy Duraloc Option cup and DePuy Articul/EZE ceramic femoral head. (Doc. 1 at ¶ 4). Defendant represents on its website that the femoral head is "comprised of high-purity aluminum oxide ceramic to provide high hardness for extreme wear." (*Id.* at ¶ 23). Defendant states that the product allows for "precise polishing to provide exceptionally smooth articulating surfaces for optimum wear resistance." (*Id.*) Defendant notes that these characteristics are important because "[l]ong term resistance to wear is a critical component of successful THA [total hip arthroplasty]." (*Id.*)

Defendant's Articul/EZE ceramic femoral head is considered a Class II medical device under 21 CFR §§ 860 and 888.3353. (*Id.* at ¶ 16). In May 1995, Defendant submitted a § 510(k) premarket notification approval for its Articul/EZE ceramic femoral head to the FDA and was granted market approval on June 30, 1995 (*Id.* at ¶ 17-18). However, Plaintiff alleges that Defendant failed to establish and maintain current good manufacturing practices with respect to quality audits, quality testing, and process validation for its Articul/EZE product. (*Id.* at ¶ 53-57).

On November 12, 2007, Plaintiff underwent a total hip replacement using Defendant's components. (Doc. 1 at ¶ 7). Plaintiff's left hip socket was replaced by a Duraloc Option acetabular cup and a Duraloc Option ceramic insert and the top of her femur was replaced by an Articul/EZE ceramic femoral head. *Id.* Plaintiff and/or her physician relied on Defendant's representations concerning the wear characteristics of its

product to select the DePuy Articul/EZE ceramic femoral head for implantation. (*Id.* at ¶¶ 73, 95). Approximately four years later, Plaintiff went to the emergency room complaining of popping and grinding in her left hip and an inability to bear weight on that leg. (*Id.* at ¶ 9). Although hip replacements are designed to last approximately 15 years, an x-ray revealed that the ceramic femoral head was broken and Plaintiff underwent revision surgery during which the ceramic cup liner and femoral head were replaced by new components. (*Id.* at ¶ 9-11). Plaintiff's surgeon confirmed that Defendant's product had fractured and noted that ceramic fragments had to be removed from Plaintiff's body. (*Id.* at ¶ 10).

II. STANDARD OF REVIEW

A motion to dismiss pursuant to Fed. R. Civ. P. 12(b)(6) operates to test the sufficiency of the complaint and permits dismissal of a complaint for "failure to state a claim upon which relief can be granted." To show grounds for relief, Fed. R. Civ. P. 8(a) requires that the complaint contain a "short and plain statement of the claim showing that the pleader is entitled to relief."

While Fed. R. Civ. P. 8 "does not require 'detailed factual allegations,' . . . it demands more than an unadorned, the-defendant-unlawfully-harmed-me accusation." *Ashcroft v. Iqbal*, 556 U.S. 662, 129 S.Ct. 1937, 1949 (2009) (citing *Bell Atl. Corp. v. Twombly*, 550 U.S. 544 (2007)). Pleadings offering mere "'labels and conclusions' or 'a formulaic recitation of the elements of a cause of action will not do." *Id*. (citing

Twombly, 550 U.S. at 555). In fact, in determining a motion to dismiss, "courts 'are not bound to accept as true a legal conclusion couched as a factual allegation[.]" *Twombly*, 550 U.S. at 555 (citing *Papasan v. Allain*, 478 U.S. 265 (1986). Further, "[f]actual allegations must be enough to raise a right to relief above the speculative level[.]" *Id*.

Accordingly, "[t]o survive a motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" *Iqbal*, 129 S.Ct. at 1949. A claim is plausible where "plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Id*. Plausibility "is not akin to a 'probability requirement,' but it asks for more than a sheer possibility that a defendant has acted unlawfully." *Id*. "[W]here the well-pleaded facts do not permit the court to infer more than the mere possibility of misconduct, the complaint has alleged—but it has not 'show[n]'—'that the pleader is entitled to relief,'" and dismissal is warranted. *Id*. (citing Fed. R. Civ. P. 8(a)(2)),

III. ANALYSIS

A. Negligence, Breach of Express Warranty, and Breach of Implied Warranty Claims

Plaintiff does not contest that Count IV (Negligence), Count V (Breach of Express Warranty), and Count VI (Breach of Implied Warranty) are abrogated by the Ohio Product Liability Act (OPLA) and as such does not oppose Defendant's motion to dismiss

these claims. Counts IV, V, and VI of the Complaint are therefore appropriately dismissed. (Doc. 1 at 17-20).

B. Negligent Misrepresentation Claim

The OPLA broadly defines "product liability claim" to include "[a]ny warning or instruction, or lack of warning or instruction, associated with that product. O.R.C. § 2307.71(A)(13)(b). This broad definition demonstrates a legislative intent that all claims arising from the manufacturing, marketing, warning, warranty, or representation of a product are claims exclusively defined, remedied, and governed by the OPLA. *Jones v. Walker Mfg. Co.,* No. 97301, 2012-Ohio-1546 (Ohio Ct. App. April 5, 2012); *Luthman v. Minister Supply Co.*, No. 2-06-43, 2008-Ohio-165, ¶ 13 (Ohio Ct. App. Jan 22, 2008).

Although this Court has found that claims for fraud or negligent misrepresentation may fall outside the scope of the OPLA's abrogation, such an exception only applies when the claims in question are grounded in the Uniform Commercial Code or "implicate the more general duty not to deceive, rather than a duty to warn." *CCB Ohio LLC v. Chemque, Inc.*, 649 F. Supp. 2d. 757, 764-65 (S.D. Ohio 2009); *Piskura v. Taser Int'l*, No. 1:10-cv-248, 2012 WL 5378805, at *19 (S.D. Ohio Oct. 29, 2012); *Stratford v. Smithkline Beecham Corp.*, No. 2:07-cv-639, 2008 U.S. Dist. LEXIS 84826 at *23 (S.D. Ohio June 17, 2008). Courts in the Sixth Circuit have largely found that the OPLA

abrogates negligent misrepresentation claims.[1]

The 2005 and 2007 amendments to the OPLA "specify that the legislature's intent in enacting the OPLA was 'to abrogate all common law product liability cases of action.'" *Piskura*, 2012 WL 5378805, at *19 (citing *Wimbush v. Wyeth*, 619 F.3d 632, 637 (6th Cir. 2010). Although Plaintiff suggests that her negligent misrepresentation claim is not abrogated because it implicates a more general duty not to deceive rather than a duty to warn, in reality Plaintiff's claim is not based on Defendant's alleged active deception, but on Plaintiff's allegation that in the exercise of reasonable care, Defendant should have known of the condition of its product. This is functionally an alleged failure to warn, and Plaintiff's negligent misrepresentation claim is abrogated.

Furthermore, even if fraud *were* implicated in Plaintiff's claim, Fed. R. Civ. P. 9(b) requires that the circumstances constituting fraud must be stated with particularity. As the Sixth Circuit instructs, this requires "the plaintiff, at a minimum, to 'allege the time, place, and content of the alleged misrepresentation on which he or she relied; the fraudulent scheme; [and] the fraudulent intent of defendant[.]" *Stratford*, 2008 WL

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[1] *Piskura*, 2012 WL 5378805, at *19 (citing *Thompson v. Sunbeam Prod.*, No. 2:10-cv-98, 2011 WL 4502049, at *15 (S.D. Ohio Sept. 28, 2011)) (claims of misrepresentation regarding warnings of products are abrogated by § 2307.76 of the OPLA); *Deacon v. Apotex Corp.*, No. 3:07-cv-322, 2008 WL 2844652, at *4 (S.D. Ohio July 22, 2008) (same); *Miler v. Alza Corp.*, 759 F. Supp. 2d 929, 943-44 (S.D. Ohio 2010) (common law negligent misrepresentation claims not specifically raised under the Uniform Commercial Code are abrogated by the OPLA); *Delman v. City of Cleveland Heights*, 41 Ohio St. 3d 1, 4 (1989) (negligent misrepresentation claim permits recovery only for pecuniary loss in business transaction caused by reliance on information provided by defendant).

2491965 at * 8 (citing *Yuhasz v. Brush Wellman, Inc.*, 181 F. Supp. 2d 785, 788 (N.D. Ohio 2001) (citing *Coffey v. Foamex, L.P.*, 2 F.3d 157 (6th Cir. 1993)). Plaintiff has alleged none of the above and therefore her negligent misrepresentation claim is appropriately dismissed even if not preempted by the OPLA.

C. Strict Liability Claims

1. Preemption

The ceramic femoral head is a Class II medical device. (Doc. 1 at ¶ 16). "Class II devices are those possessing a greater potential dangerousness and thus warranting more stringent controls." *Buckman v. Plaintiff's Legal Committee*, 531 U.S. 341, 344 (2001); 21 U.S.C. § 360(c)(a)(1)(C)(ii)(II). Class II devices reach the market through the 510(k) process. (Doc. 1 at ¶ 16). In the course of this process, a manufacturer must provide "proposed labels, labeling and advertisements sufficient to describe the device, its intended use, and directions for use," and show that "the device is similar to and/or different from other products of comparable type in commercial distribution." *Buckman*, 531 U.S. at 345 (quoting 21 C.F.R. § 807.87(e) & (f)). However, no private right of action exists for violations of federal regulations such as this. *Id.* at 349 n.4; *see* 21 U.S.C. § 337(a) ("[A]ll such proceedings for the enforcement, or to restrain violations, of this chapter shall be by name of the United States").

Plaintiff's strict liability claims are not, at base, claims for violation of federal law, however. Although Plaintiff adds an "and/or" clause mentioning Defendant's alleged

failure to comply with federal requirements to each of her strict liability claims, she ultimately brings those claims based on well-established state law manufacturing, design, and marketing duties. Plaintiff does not allege any cause of action for fraud nor that Defendant fraudulently misrepresented facts to the FDA during the premarket notification process for marketing approval of the device in question. Plaintiff's claims stem not from a duty of Defendant to the FDA to abide by federal regulations, but from Defendant's duty to Plaintiff not to sell a product that is defectively manufactured or designed or to make inaccurate representations about said product.

Under *Buckman*, implied preemption is appropriate in the case of a relationship that "originates with, is governed by, and terminates according to federal law." 531 U.S. at 347. In contrast, the relationship in question in the case at hand is the one between medical device manufacturer and patient, a relationship that originates with, is governed by, and terminates according to state law. "While there may not be a 'traditional state tort law' claim for an 'adulterated' product in so many words, the federal definition of adulterated medical devices is tied directly to the duty of manufacturers to avoid foreseeable dangers with their products by complying with federal law." *Bausch v. Stryker Corp.*, 630 F.3d 546, 557 (7th Cir. 2010), *cert. denied*, 132 S.Ct. 498 (2011). Plaintiff's "evidence showing a violation of federal law shows that the device is adulterated and goes a long way toward showing that the manufacturer breached a duty under state law toward" Plaintiff. *Id.* Plaintiff's claims in question are that Defendant

breached well-recognized state law duties owed to her through conduct that is also a violation of federal law, and are these claims are therefore not preempted by *Buckman*.

2. Pleading Sufficiency

As discussed *supra*, the pleading standard articulated in *Twombly* and *Iqbal* requires that "[f]actual allegations in the complaint must be enough to raise a right to relief above the speculative level on the assumption that all of the allegations in the complaint are true." *Twombly*, 550 U.S. at 555 (internal citations omitted). This requires "more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do." *Id.* Thus, "more than an unadorned the-defendant-unlawfully-harmed-me accusation" is required. *Iqbal*, 556 U.S. at 678 (citing *Twombly*, 550 U.S. at 555). However, "[t]he federal rules still provide for notice pleading, not fact pleading, and *Iqbal* and *Twombly* did not change that fundamental truth." *Clark v. Wright Med. Tech., Inc.*, No. 3:11-cv-162, 2011 U.S. Dist. LEXIS 74248, at *6 (S.D. Ohio July 11, 2011).

a. Manufacturing and Design Defect Claims

As this Court has established, the pleading requirements for a defective design or defective manufacturing claim are satisfied when the plaintiff alleges "that Plaintiff had Defendant's hip replacement parts surgically implanted, that the hip replacement parts broke while implanted and that Defendant's products can be identified[.]" *Foust v. Stryker Corp.*, No. 2:10-cv-5, 2010 U.S. Dist. LEXIS 69771, at *12 (S.D. Ohio June 22, 2010); *see also Clark*, 2011 U.S. Dist. LEXIS 74248 at *5 (holding pleadings sufficient if

plaintiff alleges that "the [replacement hip] broke either because it was defectively manufactured or defectively designed and . . . [the plaintiff has pled] with specificity what portion of the product failed when it failed."). Pleadings that contain these facts are more than threadbare recitals or formulaic recitations of the elements of a claim, and they "contain sufficient factual matter, accepted as true, to state a claim for relief that is plausible on its face." *Clark*, 2011 U.S. Dist. LEXIS 74248 at *5 (quoting *Courie v. Alcoa Wheel & Forged Products*, 577 F.3d 625, 629-30 (6th Cir. 2009)).

Plaintiff's complaint adequately pleads the facts held as sufficient in *Foust* and *Clark* to state a plausible claim that Defendant's hip implant was defective in manufacture and/or design. Plaintiff pleads and references good manufacturing practices that Defendant is required to maintain, including establishing and maintaining quality audits, quality testing, and process validation for the Articul/EZE ceramic femoral head, and that here, in their absence, the product was defective and failed, resulting in a fracture of the ceramic femoral head and injuries to the Plaintiff. (Doc. 1 at ¶ 55-56).

Specifically, Plaintiff pleads that Defendant designed, manufactured, sold, distributed, and suppled the Articul/EZE ceramic femoral head into the stream of commerce, that it was defective when it left Defendant's hands, and that it reached Plaintiff on November 12, 2007 when she underwent a left total hip replacement. (*Id.* at ¶ 7, 61, 66, 72). Moreover, Plaintiff identifies each individual implanted piece of Defendant's hip replacement device, including the piece that failed, the ceramic femoral

head. (*Id.* at ¶ 7). Plaintiff pleads that she learned that the ceramic femoral head had fractured inside her after months of discomfort and pain, that because of this she underwent revision surgery on October 12, 2011, and that afterward her surgeon confirmed the fracture of the component and indicated that ceramic fragments were removed from Plaintiff's body. (*Id.* at ¶ 10). These facts are incorporated into each of Plaintiff's counts and are sufficient to state claims for relief for defective manufacturing and defective design.

Defendant's assertions that Plaintiff's claims are inadequately pled because she does not currently have the device in question or because her surgeon's assembly of the hip implant device rendered the product substantially altered are also unavailing. The unavailability of a medical device is not fatal to Plaintiff's claims if she can otherwise present circumstantial evidence of the alleged defect. *Evans v. Hanger Prosthetics & Orthotics, Inc*., 735 F. Supp. 2d 785, 795 (N.D. Ohio 2010) (citing O.R.C. § 2307.73(B)). Similarly, to be termed a substantial alteration, the change to Defendant's device must have been "independent of the expected and intended use to which the product is put." *Aldridge v. Reckart Equip. Co.*, 2006 Ohio 4964, at ¶ 24 (4th Dist. 2006) (quoting *Kobza v. General Motors Corp*., 64 Ohio App. 3d 742, 745 (8th Dist. 1989)). Here, the assembly of the Articul/EZE ceramic femoral head with the other component parts of the total hip implant by an orthopedic surgeon was the expected and intended use for the femoral head. Neither Plaintiff's loss of the device nor Plaintiff's surgeon's assembly of

her hip replacement render her design or manufacturing claims inadequately pled.

b. Nonconformance with Representations Claim

Defendant is liable for nonconformance with its representations about its product under O.R.C. § 2307.77, if (1) Defendant made a representation as to a material fact concerning the character or quality of the femoral head; (2) the femoral head failed to conform to that representation; (3) Plaintiff and/or her physician justifiably relied on that representation; and (4) Plaintiff's and/or her physician's reliance on Defendant's representations was the direct and proximate cause of Plaintiff's injuries. *Cervelli v. Thompson/Center Arms*, 183 F.Supp 2d 1032, 1045 (S.D. Ohio 2002).

Defendant describes highly specific and important wear characteristics of its products. Defendant represents that its Articul/EZE ceramic femoral head is "comprised of high-purity aluminum oxide ceramic to provide high hardness for extreme wear." (Doc. 1 at ¶ 23). Defendant states that the product features "precise polishing to provide exceptionally smooth articulating surfaces for optimum wear resistance" and explains that these characteristics are important because "[l]ong term resistance to wear is a critical component of successful THA." *Id.* Defendant's statements about the ceramic femoral head's durability do not stand alone, but instead are accompanied by scientific studies and research substantiating these claims. While unsubstantiated and subjective descriptions of a product as "strong" or "rock-solid" are insufficient to form express representations, here, by contrast, Defendant's representations are highly specific and detailed

descriptions about the make-up and expected performance of the product. *Jordan v. Paccar, Inc.*, 37 F.3d 1181, 1185 (6th Cir. 1994). Defendant's statements stand as representations about the characteristics the product will exhibit and how it will perform.

Plaintiff pleads that she and/or her physician justifiably relied of Defendant's representations about the wear characteristics of Defendant's product in choosing the Articul/EZE ceramic femoral head. (Doc. 1 at ¶ 73). Additionally, Plaintiff pleads that Defendant's representations were false and the femoral head fractured inside her body. (*Id.* at ¶ 10). Consequently, Plaintiff has sufficiently pled facts to state a cause of action for nonconformance with representations.

D. Punitive Damage Claims

Plaintiff seeks punitive damages on all her tort claims. (Doc. 1 at ¶¶ 63, 69, 75, 82, and 97). Under Ohio law, punitive damages are precluded if the device "was manufactured and labeled in relevant and material respects in accordance with the terms of an approval or license issued by the federal Food and Drug Administration under the 'Federal Food, Drug, and Cosmetic Act.'" O.R.C. § 2307.80(C). Although the fact that Defendant received marketing approval does not establish that Defendant's product was actually manufactured and labeled in accordance with that approval, Plaintiff must allege facts to show a lack of the required compliance.

Here, Plaintiff pleads that, in conflict with the requirements of the 510(k) approval process, the Articul/EZE ceramic femoral head was adulterated because the product failed

to meet performance standards, that Defendant failed to establish and maintain current good manufacturing practice with respect to quality audits, quality testing, and process validation, and that as a result of Defendant's failure to maintain such standards as required by the 510(k) approval process, the device failed and caused Plaintiff's injuries. (Doc. 1 at ¶¶ 53-57). Plaintiff pleads that the ceramic femoral head was defective in manufacture and construction in that it deviated from product specifications. (*Id.* at ¶¶ 61-62).

Accordingly, construing the complaint in the light most favorable to Plaintiff, the allegations set forth therein sufficiently state a claim for punitive damages.

IV. CONCLUSION

Based on the foregoing, Defendant's Motion to Dismiss (Doc. 7) is **GRANTED IN PART AND DENIED IN PART**. Specifically:

1. Defendant's Motion to Dismiss Counts I, II, and II (strict products liability: defective manufacturing, strict products liability: design defect, and strict products liability: defect due to nonconformance with representations) is **DENIED**.

2. Defendant's Motion to Dismiss Counts IV, V, VI, and VII (negligence, breach of express warranty, breach of implied warranty, and negligent misrepresentation) is **GRANTED**.

3. Defendant's Motion to Dismiss Plaintiff's punitive damage claims is **DENIED**.

IT IS SO ORDERED.

Date: 5/2/13

s/ Timothy S Black

Timothy S. Black

United States District Judge